REMARKS

Applicants have reviewed the nonfinal Office Action of October 5, 2007. Claims 1, 4, 5, 11, 13, 16, 19, 20, 25, 26, 30, and 32 have been amended. Claims 3, 23, and 24 have been cancelled. Claims 6-8, 17, and 27 are withdrawn. Claims 1, 2, 4, 5, 11-16, 18-22, 25, 26, and 30-34 are pending. Reconsideration is requested.

Claim 24 was objected to. Claim 24 has been cancelled for reasons unrelated to this objection. As this objection is now moot, Applicants request its withdrawal.

Claims 1-5, 11-16, 18-26, and 30-34 were rejected under 35 U.S.C. 112, first paragraph, as allegedly failing the enablement requirement on two different bases. Applicants traverse the two enablement rejections.

In the first enablement rejection, the Examiner stated that while the specification was enabling for a protein-based film forming from an interchange reaction at pH 3.5-7.0, it was not enabling for any pH below 7.0.

In response, Applicants submit that based on the *Wands* factors, undue experimentation is not required. According to the Examiner, the quantity of experimentation would be large since any pH below 7.0 can be chosen. However, the Examiner agrees that the specification is enabling for pH 3.5-7.0. In other words, the relevant range would be any pH below 3.5; this narrows the amount of experimentation needed and the first *Wands* factor leans towards enablement.

The specification provides a large amount of direction and guidance. The Examiner has cited pg. 9, lines 11-13 and Example 11. Applicants note that pg. 9, lines 8-13 disclose a pH range of 2-7, not just 4.5-7.0 as the Examiner stated, as emulsions can also be used to form the protein-based films. This text also notes that the film formation should be carried out at "acidic" pH, which describes the entire range of pHs below 7.0. The table on page 14 provides information on temperature and exposure time. Page 17, lines 3-26 provides additional information. Finally, Applicants note Examples 10-12, which are carried out at pHs 6.5, 3.5, and 6.0, respectively. These three Examples provide guidance because they each follow the same steps, except for

the adjustment of pH. This consistency of procedure provides direction to one of skill in the art. Thus, the second *Wands* factor leans towards enablement.

There are several working examples. Thus, the third *Wands* factor leans towards enablement.

According to the Examiner, the nature of the invention is such that a change in the pH environment may disrupt the film formation process. The Examiner also stated that the state of the prior art is that proteins are sensitive to their environment. The Examiner also stated that the predictability as to which pH values above 7.0 will initiate film formation is zero. These three statements are true, but ignore the disclosure that the change in pH environment is based on whether the pH is acidic or alkaline, not based on degrees of acidity. See pg. 9, lines 8-13. Applicants also note that the claims require the pH value be 7 or below, not above 7.0 Thus, the fourth, fifth, and seventh *Wands* factors lean towards enablement.

According to the Examiner, the relative level of skill in this art is very high. This suggests, however, that less disclosure is needed, not more. Thus, the sixth *Wands* factor leans towards enablement.

As discussed above, the *Wands* factors lean towards enablement for all pH values of 7 or below. Applicants request withdrawal of this basis for rejection.

In the second enablement rejection, the Examiner stated that it would require undue experimentation to determine which proteins contain disulfide bonds. In response, Applicants submit that it would not require undue experimentation.

The quantity of experimentation would not be large. In particular, methods for determining the presence of disulfide bonds in a protein are known in the art. For example, a protein can be submitted to enzymatic treatment and the resulting fragments subjected to electrophoresis, wherein the difference in size between the original protein and the fragments indicate the presence of disulfide bonds. Alternatively, the disulfide bonds can be broken and the denatured protein again subjected to electrophoresis that distinguishes between long amino acid chains (denatured) and active, folded protein. This *Wands* factor thus leans towards enablement. Alternatively, various protein databases can also be searched to determine which proteins contain disulfide bonds.

The amount of guidance is minimal, but this factor is balanced by the fact that the relative level of skill in the art is high.

According to the Examiner, the nature of the invention is such that the protein structure is essential to forming the disulfide bond network. This statement is incomplete. In particular, the claims do require a protein that contains disulfide bonds, but the order and identity of the other amino acids in the protein do not matter. Since one of ordinary skill in the art can identify such proteins, this *Wands* factor leans towards enablement.

According to the Examiner, the state of the prior art is that even proteins 99% similar to wild-type protein are at times not fully active. The Examiner noted Example 1, wherein whey protein is the modified protein in solution to activate lactalbumin. It appears that the Examiner is interpreting the term "activated" to require that the protein be able to perform some activity or function. However, Applicants use the term "activated" to refer only to the fact that the protein now has free sulfhydryl groups which are free to react with other sulfhydryl groups. In other words, the state of the prior art does not appear to be relevant here, as Applicants disclose methods to render any protein containing disulfide bonds active. Applicants do not require the protein to have previously been able to perform any function and then retain that ability (e.g., any enzymatic cleaving ability). In addition, Applicants do not require 100% conversion of disulfide bonds to free sulfhydryl groups. As the specification notes, the modification process may not modify all protein. See page 8, lines 16-22. Thus, this *Wands* factor leans towards enablement.

As discussed above, the *Wands* factors lean towards enablement for ascertaining which proteins can form a disulfide bond network. Applicants request withdrawal of this basis for rejection.

For these reasons, Applicants request withdrawal of the two enablement rejections.

Claims 1-5, 11-16, 18-26, and 30-34 were rejected under 35 U.S.C. 112, first paragraph, because the Examiner alleged that they referred to proteins only by function. This appears to be a written description rejection. Applicants traverse the rejection.

According to the Examiner, Applicants are claiming proteins by what it does, i.e. function, rather than what it is, i.e. in structure. In response, Applicants submit that the Examiner is incorrect. First, Applicants are not claiming specific proteins; instead, Applicants are claiming a network that can be formed from proteins. Second, Applicants have described those proteins based on structure, not function. To be able to form the claimed network, the proteins must contain a disulfide bond. A disulfide bond is a structure, not a function. A disulfide bond has the structure: R-S-S-R. Proteins containing a disulfide bond can be used to form the protein network, regardless of what function that protein can perform. The presence of a disulfide bond distinguishes such proteins from those that do not contain a disulfide bond.

Applicants request withdrawal of the written description rejection.

Claims 1-5, 11-16, 18-26, and 30-34 were rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite. Applicants traverse the rejection.

The Examiner requested that Applicants clarify between proteins in the network, proteins comprising a protein network, modified proteins. The Examiner stated that it was unclear whether the interchange reaction took place between modified proteins, network proteins, or network proteins and modified proteins. The Examiner also stated that it was unclear what was meant by "forming" in claim 20.

Applicants have amended claim 1 to clarify that the network is formed by disulfide bonds between modified and unmodified proteins. Claim 20 has been amended to clarify that the modified proteins cause the formation of the disulfide bonds.

As to "forming" in claim 20, the specification describes multiple methods of making a film from the solution. For example, page 9, lines 14-23 describe forming a film on a substrate; page 12, lines 5-20 describe spraying the solution to form a film; page 18, lines 15-26 describe brushing, spreading, dipping, spraying, and suspension coating. All of these methods are intended to be encompassed by claim 20.

The Examiner stated that there was insufficient antecedent basis for "the pH" in claim 1. This point is moot as a result of the amendments to claim 1.

The phrase "such as" has been removed from claims 4, 5, and 26

Claims 11 and 30 have been amended to clarify that there is only one substance.

Claim 13 has been amended to remove the phrase "or the like."

The Examiner stated that claims 15 and 34 were unclear because a lipophilic compound was not defined or identified. In response, Applicants assert that the term "lipophilic compound" defines itself. The word "lipophilic" is known to refer to "fat-loving" compounds and one of ordinary skill in the art would understand its meaning. The specification also gives examples of lipophilic compounds, such as soya oil or other oils (pg. 13, lines 25-27); stearates (pg. 17, lines 27-30); and aromatic agents and spices (pg. 19, lines 16-19). Applicants submit that this term is thus definite.

Applicants request withdrawal of the indefiniteness rejection.

Claims 1-5, 11-16, 18-26, and 30-34 were rejected under 35 U.S.C. 103(a) as allegedly being obvious over Krochta '164 (U.S. Patent No. 5,543,164) in view of Krochta '628 (U.S. Patent No. 6,869,628). Applicants traverse the rejection.

The combination of references does not disclose all claim elements of amended claim 1. MPEP § 2143.03. In particular, claim 1 now recites that the network contains from about 2 to about 4 free sulfhydryl groups per protein. Support for this amendment can be found on pg. 13, lines 14-20 of the specification. Krochta '164 also appears to teach that any remaining free thiol groups should be oxidized. See col. 5, lines 44-48. This teaches away from amended claim 1.

There is no motivation to combine the references to arrive at claim 20. MPEP § 2143.01. Claim 20 has been amended to require the use of sulfite ion forming agent at a pH of 7 or below. On page 9, the Examiner stated that Krochta '164 discloses that enzymatic treatment can be carried out with enzymes that function optimally at a pH of 7. While this disclosure may provide motivation to use a pH of 7 when enzymes are used to form the disulfide bonds, it does not provide motivation to use a pH of 7 if enzymes are not used. Krochta '164 and Krochta '628 do not appear to discuss pH at all in regards to any treatment using sulfite ion forming agent and therefore cannot render obvious claim 20.

For at least these reasons, Applicants request withdrawal of the § 103(a) rejection based on Krochta '164 and Krochta '628.

CONCLUSION

For at least the reasons detailed above, it is respectfully submitted all claims remaining in the application (Claims 1, 2, 4, 5, 11-16, 18-22, 25, 26, and 30-34) are now in condition for allowance.

In the event the Examiner considers personal contact advantageous to the disposition of this case, the Examiner is hereby authorized to call Jay F. Moldovanyi, at telephone number 216-861-5582, Cleveland, OH.

Respectfully submitted,

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November 30, 2007
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Date: November 30, 2007	Name: Lynda S. Kalemba

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